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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/820,649	03/30/2001	Steven M. Ruben	PZ012P1C2	6561

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HUMAN GENOME SCIENCES INC
INTELLECTUAL PROPERTY DEPT.
14200 SHADY GROVE ROAD
ROCKVILLE, MD 20850

EXAMINER	
MITRA, RITA	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 06/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/820,649	RUBEN ET AL.	
	Examiner	Art Unit	
	Rita Mitra	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 March 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17,19,20 and 25-34* is/are pending in the application.

4a) Of the above claim(s) *17, 19, 20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/31/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

Applicants' amendment in response to office action dated December 31, 2003 filed on March 31, 2004, is acknowledged. Exhibits A and B attached to the 'Response under 37 C.F.R. 1.111' are acknowledged. Withdrawn claims 17, 19 and 20 have been amended and entered. However, the amended claims 17, 19 and 20 are still process claims depending from the product claim 30. Regarding joining the process claims with the product claims, Applicants' attention is drawn to the office action dated 12/31/2003 at page 4. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so**

may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

In view of the foregoing, amended claims 17, 19 and 20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a non-elected invention. Therefore, claims 25-34, SEQ ID NO: 105; Gene 4 (HAUAQ39) are examined on the merits. Therefore, claims 25-34 are currently pending and are under examination.

Response to Remarks and arguments

Priority Date:

The objection to claiming the filing date of July 30, 1997 of parent application 60/054212 as the priority date is withdrawn in view of Applicants' comments on page 6 and Exhibit A.

Rejections under 35 USC § 112, First Paragraph

The rejection of claims 25-34 under 35 USC § 112, First Paragraph is withdrawn in view of a declaration regarding availability of the deposit made to ATCC and the ATCC deposit receipt (Exhibit B) and remarks at page 11.

Rejections under 35 USC § 102 (b)

The rejection of claims 27 and 32 under 35 USC § 102(b) as anticipated by Collins et al. is withdrawn in view of the response and remarks on pages11-12 of 'Amendment and Response.'

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title"

Claims 25-34 are/remain rejected under 35 U.S.C. 101 because the specification does not provide either a specific or substantial asserted utility or a well-established utility, and thus, does not support the claimed invention. The claimed proteins are not supported by either a specific asserted utility or a well established utility because the specification fails to assert any utility for the claimed polypeptides or the encoded proteins and neither the specification as filed, nor any art of record discloses or suggests any activity for the claimed polypeptides or the encoded proteins such that another non-asserted utility would be well established. Note, because the claimed invention is not supported by a specific asserted utility for the reasons set forth above, credibility cannot be assessed.

The specification, on page12 (gene 4) and page 127 (Table 1) describes clone HAUAQ39 (ATCC NO: 209145) to which the instant invention relates. The specification also asserts (page 12) that the polypeptides and polypeptides encoded by the polynucleotides of the invention are useful as reagents for differential identification of the tissues or cell types present in a biological sample and for diagnosis of diseases and conditions, which include osteoporosis or any of a variety of diseases that involve wasting of bone or muscle. Further specification indicates that for a number of disorders of the tissues or cells, particularly skeletal and muscular systems, expression of this gene may be routinely detected, relative to the standard gene expression level, i.e., the expression level in healthy tissue or cell. However, the specification fails to provide any description of how to use such tissue or cells for expression or how such expression would have been assessed. In this regard, it is noted that pages 12-13 refer to various tests and diseases, but there is no explanation of, e.g., how or what would have been affected by the polypeptide, or how one would have used such information gleaned from expression or data from any tests or assays. For example, the specification asserts that expression in muscular tissue indicates that polypeptides expressed therein are useful for the detection, treatment, and/or prevention of various muscle disorders, such as muscular dystrophy, cardiomyopathy, fibroids, myomas, rhabdomyosarcomas, as well as diseases involving wasting of the muscular tissue.

Based on the specification (pages 12-13), no biological activity has been set forth for the polypeptide of clone HAUAQ39 nor has any use for the polypeptide itself been provided. Only speculative biological activities have been provided on page 154-161 and 161-167 of the

specification. In examples 1-29, it appears that these experiments have not been performed. The examples are not written in the past tense. Therefore, they appear to be prophetic examples ((MPEP 608.01 (p)). For example, the use of the protein for further research is described here (page 154-159). This use is not a patentable utility because one skilled in the art should not have to discover for themselves the use of the claimed proteins. This situation requires carrying out future research to identify or reasonably confirm a "real world" context of use and therefore does not define specific and substantial utility.

The specification at page 167 indicates that the polynucleotides or polypeptides can be used as a nutritional source of polypeptides. This use is considered to be a "throw away" utility and does not distinguish the claimed polypeptide over any other polypeptide. The utility is not specific or substantial.

Other activities that the protein is asserted to exhibit are listed throughout page 157-159 of the specification. However, these activities are speculative absent factual scientific data to demonstrate same. In summary, the polypeptides and encoded proteins claimed do not have a credible, specific or well-established or even demonstrable utility and therefore lack utility under 35 U.S.C. 101.

Claims 25 and 26 are drawn to an isolated protein comprising amino acid residues 2-220 of SEQ ID NO: 105 and amino acid residues 1-220 of SEQ ID NO: 105 respectively. The specification does not describe the functional properties of the entire full-length protein or its mature form nor of any fragments thereof, and the structural information is limited (see next paragraph). While the specification enumerates several known assays for biological activity (p. 189-208, Examples 11-22), it does not guide the selection of a specific assay that would have been used to screen the biological activities of the claimed polypeptides for which no known activity is explicitly disclosed nor demonstrated.

Claims 30 and 31 are drawn to proteins encoded by the cDNA of clone HAUAQ39. It is not apparent from the description of the clone (specification page 12-13) what is the protein structure, aside from its amino acid sequence, and/or its function. Based on the specification

(page 12-13, 161-167) it is not apparent what activity the claimed protein possesses or how a person skilled in the art would have used the claimed protein based on the disclosure

Claims 27 and 32 are drawn to a protein of claims 25 and 30 respectively, which comprises a heterologous polypeptide sequence. The specification fails to provide a description of the structure, and /or function of the heterologous protein. Without any description of the unrelated sequence that has recombined with the gene how one would know the utility of the heterologous polypeptide.

Claims 28 and 33 are directed to a composition comprising the protein of claims 25 and 30 respectively and a pharmaceutically acceptable carrier. The speculative composition and their administration and dosage are listed in the specification (pages 208-210, Example 23), however, when the proteins claimed lack a credible, specific or well established utility and method of use, the composition of those proteins would also lack utility under 35 U.S.C. 101. Applicants assert on page 208 that the composition would be useful in the treatment of conditions associated with disease. Examples of many therapeutic methods have been described in pages 208-210 but the specification does not indicate explicitly the correlation of the role of the protein or the composition containing the protein to a specific disease treatment, nor demonstrate the successful treatment of any disease or conditions.

Claims 29 and 34 are drawn to a protein produced by the method comprising expressing the protein by a cell and recovering the protein. Specification on page 152-154 describes the vectors and host cells but does not indicate the function of the expressed protein.

In the instant case, the failure of the specification to specifically identify why the claimed invention is believed to be useful renders the claimed invention deficient under 35 USC 101. No specific biological activity has been identified for the protein set forth in SEQ ID NO: 105 other than a statement that the polypeptides of the invention are useful as reagents for differential identification of tissues (p. 12 and Example 3), however specification has not demonstrated the tissue distribution. The person having ordinary skill in the art would not be able to identify any specific activity for the protein comprising or related to SEQ ID NO: 105 based on its structure alone for the reasons set forth above. General statements that a composition has an unspecified biological activity or that does not explain why a composition with that activity is believed to be

useful fails to set forth a "specific utility." Brenner v. Manson, 383 US 519, 148 USPQ 689 (Sup. Ct.1966) (general assertion of similarities to known compounds known to be useful without sufficient corresponding explanation why claimed compounds are believed to be similarly useful is insufficient under 35 USC 101).

The rejection has been set forth in the previous office action. In response, applicants traverse the foregoing rejection and argue (pages 7-8) that in order to find that an asserted utility is not specific and substantial or well-established, the burden is on Examiner to make a prima facie showing that it is more likely than not that a person of ordinary skill in the art would not consider any utility asserted by the Applicant to be specific and substantial or well-established (MPEP 2107.02 (IV)) (page 7). With regard to evaluating if an invention has a "specific" utility, applicants have cited MPEP 2107.01, pages 2100-32 (more specifically page 2100-25, col. 1, lines 23-35), where it is stated that (see Applicants' remarks, page 7, last 13 lines),

"Office personnel should distinguish between situations .....for the invention"

However, Applicants should also note the citation further reads on lines 36-40 that "assertions that fall in the former category are insufficient to define a specific utility for the invention, especially if the assertion takes the form of a general statement that makes it clear that a "useful" invention may arise from what has been disclosed by the applicant." The specification also asserts (page 12) that the polypeptides and polypeptides encoded by the polynucleotides of the invention are useful as reagents for differential identification of the tissues or cell types present in a biological sample and for diagnosis of diseases and conditions, which include osteoporosis or any of a variety of diseases that involve wasting of bone or muscle. This assertion falls into the category where the assertions are insufficient to define a specific utility, because the disclosure of the structure of polypeptides and polynucleotides of clone HAUAQ39 does not provide their specific utility (see discussion supra).

Regarding "substantial utility" Applicants have stated (Remarks page 8) that the MPEP states that if a utility has a "real-world" use it should be considered to be substantial. In particular MPEP 2107.01 at page 2100-33 states that "any reasonable use that an applicant has identified for the invention that can be viewed as providing a public benefit should be accepted as

sufficient at least with regard to defining a "substantial utility." In response Applicants' should note that it was stated in the previous office action (and also supra) that based on the specification (pages 12-13 and in Examples 1-29), neither any biological activity has been set forth for the polypeptide of clone HAUAQ39 nor has any use for the polypeptide itself been provided. Only speculative biological activities have been provided on page 154-161 and 161-167 of the specification. For example, the use of the protein for further research is described here (page 154-159). This use is not a patentable utility because one skilled in the art should not have to discover for themselves the use of the claimed proteins. It should also be noted that the claimed subject matter is not supported by a specific utility because the disclosed uses are generally applicable to broad classes of this subject matter. In addition, further characterization of the claimed subject matter would be required to identify or reasonably confirm a "real world" use and therefore does not define specific and substantial utility.

Claim Rejections - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 25-34 remain/are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial or well established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention so that it would operate as intended without undue experimentation.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rita Mitra whose telephone number is (571) 272-0954. The Examiner can normally be reached from 9:30 a.m. to 6:30 p.m. on weekdays. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Christopher Low, can be reached at (571) 272-0951. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center number is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-0547

R Mitra

Rita Mitra, Ph.D.

June 12, 2004

CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600